UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LEON D. BOROCHOFF, on behalf of himself and all other similarly situated,	:	
Plaintiff,	:	CIVIL ACTION
v.	:	NO. 07-CIV-5574 (LLS)
GLAXOSMITHKLINE PLC, et al.,	:	
Defendants.	:	

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR RECONSIDERATION OF THE COURT'S MAY 9, 2008 OPINION AND ORDER

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Date: June 27, 2008

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Defendants GlaxoSmithKline plc ("GSK" or "the Company"), Jean-Pierre Garnier, Ph.D., David Stout, Julian Heslop and Simon Bicknell ("Individual Defendants") (collectively "defendants"), by their attorneys, respectfully submit this memorandum of law in opposition to plaintiffs' motion for reconsideration of the Court's May 9, 2008 Opinion and Order.[1]

I. INTRODUCTION

On May 9, 2008, this Court entered an Opinion and Order, granting defendants' motion to dismiss plaintiffs' Amended Class Action Complaint ("Amended Complaint") and denying plaintiffs leave to replead. *Borochoff v. GlaxoSmithKline*, No. 07 Civ. 5574, 2008 WL 2073421, at *10 (S.D.N.Y. May 9, 2008).[2] The Court held that the Amended Complaint failed to state a claim under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 on two separate and independent grounds: (1) that "GSK had no duty to disclose the results of its meta-analyses, and [therefore] the amended complaint [did] not sufficiently plead that defendants made a material omission," *id.* at *7; and (2) that "[t]he amended complaint [did] not adequately allege a strong inference of scienter," *id.* at *10.

The Court reasoned that GSK had no duty to disclose the meta-analyses data because the allegations of the Amended Complaint, when read in their entirety together with referenced materials (including the full contents of public statements by the FDA and GSK), did "***not*** show that the [alleged] heart attack risk was either statistically significant or sufficiently

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[1] Plaintiffs include Lead Plaintiff Avon Pension Fund, Administered by Bath & North East Somerset Council ("Avon Pension Fund" or "Avon"), and plaintiffs Plumbers & Steamfitters Local 773 Pension Fund and Plumbers' Union Local No. 12 Pension Fund.

[2] For the Court's convenience, a copy of the Westlaw publication of the Court's May 9, 2008 Opinion and Order is appended hereto as Exhibit A.

serious or frequent to affect Avandia's future earnings." *Id.* at *7 (emphasis added). As for the deficiencies in plaintiffs' scienter allegations, the Court explained:

> The amended complaint does not allege that defendants purposefully concealed known conclusive risks from the public. As discussed above, the Avandia studies and GSK's meta-analyses did not show a decisive link between Avandia and cardiovascular risks. "Because, as discussed earlier, this case does not present facts indicating a clear duty to disclose, plaintiff's scienter allegations do not provide strong evidence of conscious misbehavior or recklessness."

Id. at *9 (quoting *Kalnit v. Eichler*, 264 F.3d 131, 143-44 (2d Cir. 2001)).[3] The Court also pointed out that:

> Allegations of defendants' intent to defraud by suppressing negative data are inconsistent with defendants' disclosure of that data on GSK's website and to the FDA. GSK disclosed its meta-analyses results to the FDA, and posted them to its website, which rebuts any intent to defraud by concealing information.

Id. at *8.

In their brief in opposition to defendants' motion to dismiss, plaintiffs requested leave to replead on the basis of certain alleged "newly discovered information" they argued supported a strong inference of scienter. This information included documents allegedly suggesting that, in 1999-2000, GSK intimidated Dr. John Buse "to silence his concerns about Avandia's negative cardiovascular effects." *Id.* at *10. The Court denied plaintiffs' request, noting, *inter alia*, that the information about Dr. Buse was "not 'newly discovered,'" *id.* at *10 n.3, and, in any event, "the proposed additions to the amended complaint would be futile," *id.* at *10.

[3] The Court also held that plaintiffs failed to plead sufficient motive allegations to support a strong inference of scienter. *Id.* at *7-8.

On May 28, 2008, plaintiffs nonetheless filed the instant motion,[4] asking the Court to (a) reconsider its May 9, 2008 Opinion and Order, (b) vacate "that portion" of its decision which dismisses the Amended Complaint with prejudice, and (c) grant plaintiffs leave to further amend their allegations, as set forth in their proposed Second Amended Class Action Complaint ("Proposed Second Amended Complaint"). (Pls.' Br. at 2.)[5] At bottom, plaintiffs' motion seeks leave to add "new" allegations that supposedly are based on "newly discovered evidence" pertaining to four matters:

1. GSK's alleged intimidation of Dr. John Buse in 1999-2000;

2. The alleged showing by GSK's meta-analyses that Avandia presents a statistically significant increased risk of heart attack;

3. GSK's alleged "failure to submit Avandia-related study data to the FDA on numerous occasions;" and

4. The alleged "dramatically declining sales of Avandia."

(*Id.* at 1-2.)

As explained below, none of plaintiffs' alleged "newly discovered evidence" meets the strict criteria for vacating the Court's judgment. Indeed, most of the information proffered by plaintiffs was publicly available before the Court ruled on defendants' motion to dismiss and, therefore, is neither "new" nor "newly discovered." Because plaintiffs have failed to provide a valid basis for vacating the Court's previous decision, the Court should decline to entertain their motion for leave to amend. But even if considered, plaintiffs' proposed "new"

[4] The Court entered judgment on May 13, 2008.

[5] A copy of the Proposed Second Amended Complaint is appended as Exhibit B to plaintiffs' memorandum of law in support of their motion ("plaintiffs' brief").

allegations cannot cure the substantive pleading deficiencies that resulted in this Court's dismissal of the Amended Complaint. Thus, plaintiffs' motion should be denied.

II. ARGUMENT

A. Courts In The Second Circuit Apply A Strict Standard When Deciding Motions For Reconsideration And Will Not Entertain A Motion For Leave To Amend Unless There Is A Valid Basis For Vacating The Previously Entered Judgment

1. As Lead Plaintiff Acknowledged Earlier In This Litigation, Motions For Reconsideration "Should Be Granted Sparingly In The Interests Of Finality And Preservation Of Judicial Resources"

In the Second Circuit, motions for reconsideration are reviewed under a "strict" standard and are rarely granted. *E.g., In re Health Mgmt. Sys., Inc. Sec. Litig.*, 113 F. Supp. 2d 613, 614 (S.D.N.Y. 2000). As Lead Plaintiff Avon Pension Fund itself emphasized in its brief in opposition to the Institutional Investor Group's motion for reconsideration of the Court's decision appointing Avon as Lead Plaintiff: "Motions for reconsideration offer an extraordinary remedy and should be granted sparingly in the interests of finality and preservation of judicial resources." (Lead Pl.'s Opp. Br. to IIG's Mot. for Recons. at 3.) In addition, as Lead Plaintiff has also pointed out: "'A court must narrowly construe and strictly apply Local Rule 6.3 so as to avoid duplicative rulings on previously considered issues and to prevent the rule from being used to advance different theories not previously argued, or as a substitute for appealing a final judgment.'" (*Id.* (quoting *Thomas v. iStar Fin., Inc.*, 520 F. Supp. 2d 478, 480 (S.D.N.Y. 2007)); *see also In re Health Mgmt. Sys., Inc. Sec. Litig.*, 113 F. Supp. 2d at 614 (citing cases). Thus, a motion for reconsideration and to vacate a prior judgment may not be used to "relitigate matters settled by the original judgment." *Donovan v. Sovereign Sec. Ltd.*, 726 F.2d 55, 60 (2d Cir. 1984). Nor can it "be used to overcome counsel's tactical judgments about what evidence to

offer." *Frankel v. ICD Holdings S.A.*, 939 F. Supp. 1124, 1127 (S.D.N.Y. 1996) (citation omitted).

Here, plaintiffs do not contend that this Court made any legal error in its prior determinations. They also do not (and cannot) claim that the Court erroneously overlooked or misunderstood any of the cognizable facts. Instead, plaintiffs seek leave to add a handful of "new" allegations, based primarily on the groundless assertion that these "new" allegations reflect "newly discovered" evidence.

Where, as here, a motion to vacate a prior judgment is based on alleged "newly discovered evidence," the movant must demonstrate that:

> (1) the newly discovered evidence was of facts that existed at the time of trial or other dispositive proceeding,
>
> (2) the movant [was] justifiably ignorant of them despite due diligence,
>
> (3) the evidence [is] admissible and of such importance that it probably would have changed the outcome, and
>
> (4) the evidence [is not] merely cumulative or impeaching.

Id.

As explained below, plaintiffs have failed to meet this burden.

2. Plaintiffs Misstate The Standard For Considering A Motion For Leave To Amend Where Judgment Has Already Been Entered

Citing inapposite case law, plaintiffs contend that "[l]eave to replead is routinely granted, particularly where the party seeking leave has expressed an intention to allege additional facts." (Pls.' Br. at 7.) To the contrary, where, as here, the court has already entered judgment, "the filing of an amended complaint is not permissible until judgment is set aside or vacated pursuant to Fed. R. Civ. P. 59(e) or 60(b)." *Nat'l Petrochemical Co. of Iran v. M/T Stolt Sheaf*,

930 F.2d 240, 244 (2d Cir. 1991) (internal quotation marks and citation omitted). "Unless there is a valid basis to vacate the previously entered judgment, it would be contradictory to entertain a motion to amend the complaint." *Id.* at 245; *accord In re Star Gas Sec. Litig.*, 241 F.R.D. 428, 431 (D. Conn. 2007) (recognizing that "there must be a valid basis to vacate the previous judgment before amendment will be considered . . . ") (internal quotation marks omitted).

And while "it might be appropriate in a proper case to take into account the nature of the proposed amendment in deciding whether to vacate the previously entered judgment," *Nat'l Petrochemical Co.,* 930 F.2d at 244, "care must be taken to avoid allowing Rule 15 which liberally allows amendments of a complaint to be used to contravene the policy in favor of the finality of judgments." *Antigenics, Inc. v. U.S. Bancorp Piper Jaffray, Inc.*, No. 03-0971, 2004 WL 2290899, at *1 (S.D.N.Y. Oct. 8, 2004) (citation omitted); *accord In re Star Gas Sec. Litig.*, 241 F.R.D. at 431. Put simply, "[t]he plaintiffs do not get leisurely repeated bites at the apple, forcing a district judge to decide whether each successive complaint was adequate under the PSLRA." *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 57 (1st Cir. 2008); *see also Pugh v. Tribune Co.*, 521 F.3d 686, 698 (7th Cir. 2008) ("Courts have rejected the argument that . . . [plaintiffs] were entitled to wait and see what the district court said before making any changes to the complaint – because it would impose unnecessary costs and inefficiencies on both the courts and party opponents.").

Here, plaintiffs' proposed allegations provide no valid basis for "contravening the policy in favor of the finality of judgments." *Antigenics,* 2004 WL 2290899, at *1. First, as explained in more detail in Section II.B *infra*, plaintiffs' proposed amendments do not derive from any "newly discovered evidence." Instead, these four sets of additional averments respectively:

- Refer to information previously provided to the Court, and which the Court already considered when deciding defendants' motion to dismiss. *See Borochoff,* 2008 WL 2073421, at *10 n.3 (finding that information about GSK's alleged intimidation of Dr. Buse was "not 'newly discovered'");

- Allege public information that was readily available to plaintiffs before they filed their Amended Complaint. (*See* Pls.' Br. at 4-5 (quoting GSK's October 24, 2007 announcement of a 38% drop in sales of Avandia));

- Point to information that was publicly available over a month before the Court issued its May 9, 2008 Opinion and Order, but which plaintiffs did not elect to bring to the Court's attention or claim was significant at that time. (*See* FDA Warning Letter to GSK, March 25, 2008 (posted on FDA's website on April 8, 2008 and widely reported in the media immediately thereafter), a copy of which is appended to plaintiffs' brief as Exhibit C); and

- Are not based on any new "evidence" but merely seek to add conclusory new verbiage (*i.e.*, the words "statistically significant") characterizing otherwise identical factual allegations previously considered by the Court and held to be insufficient and unsupported when viewed in the full context of public documents referenced in the Amended Complaint. *See Borochoff,* 2008 WL 2073421, at *7 (finding that, contrary to plaintiffs' assertions, statements by the FDA did "***not*** show that the heart attack risk was either statistically significant or sufficiently serious or frequent to affect Avandia's future earnings") (emphasis added).

Second, even if plaintiffs' alleged "newly discovered evidence" were properly considered, none of it establishes a duty to disclose or supports a strong inference of scienter. Thus, none of it would have changed the outcome of this case. Having failed to present any adequate basis for vacating this Court's judgment, plaintiffs' motion should be denied.

B. Plaintiffs Have Not Demonstrated A Valid Basis To Vacate The Court's Prior Judgment

As explained in Section I *supra*, the Court dismissed plaintiffs' Amended Complaint for the separate and independent reasons that (1) plaintiffs failed to allege any duty to disclose, and (2) plaintiffs failed to allege a strong inference of scienter. Plaintiffs' motion for reconsideration fails to overcome either of these fatal flaws.

1. Plaintiffs Have Presented No Basis For Reconsidering The Court's Holding That They Failed To Allege A Duty To Disclose

Plaintiffs have asked for leave to add allegations that Avandia presented a "statistically significant" risk of heart attack. (*See* Pls. Br. at 4.) Yet they have not pointed to any "newly discovered evidence" suggesting that this is so. Instead, plaintiffs have merely added a conclusory assertion of statistical significance to their prior allegations regarding GSK's meta-analyses. (*Id.; see also* Proposed Second Amended Complaint ¶¶ 5, 6, 43-46.)

Moreover, for purposes of determining whether a duty to disclose arises, "statistical significance" is not viewed in isolation for a particular study or trial. Rather, the totality of all information, including the results of all studies, should be taken into account. This is because, as defendants explained in their motion to dismiss papers (*see* Defs.' Opening Br. at 35-42; Defs.' Reply Br. at 17-23), a duty to disclose does not attach unless and until there is sufficiently reliable scientific evidence of a causal connection between a product and the alleged "ill effects," ***and*** such ill effects "are sufficiently serious and frequent to affect future earnings." *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998). While statistical significance is a part of that inquiry, the statistical significance of a single test does not alone suffice; that is particularly true where, as here, other contrary and more reliable study evidence is available, including the observational Balanced Cohort Study and results from long-term clinical

trials (as extensively discussed in the prior motion to dismiss papers), which also were presented to the FDA. (*See* Defs.' Opening Br. at 4, 11-14, 18-21; Defs.' Reply Br. at 1-2, 6.) Otherwise, pharmaceutical companies would be required to inundate the public with any and all scientific and medical information that is considered "statistically significant" when viewed in isolation, regardless of whether such information, particularly when viewed in its scientific or medical context, is inconclusive or unreliable. *See Borochoff*, 2008 WL 2073421, at *7 (recognizing that companies should not be required to "'bury the shareholders in an avalanche of trivial information'") (quoting *San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Co.*, 75 F.3d 801, 810 (2d Cir. 1996)) (alteration omitted).

Here, the Court properly considered the FDA's public statements (referenced in the Amended Complaint) regarding the Agency's own inability to conclude that the Avandia safety data (including GSK's meta-analyses) – when viewed in their totality – showed a clinically significant increased risk of heart attacks. *Id.* at *6-7 (citing Defs.' Exh. 26, FDA Press Release, FDA Issues Safety Alert on Avandia (May 21, 2007)). As the FDA itself explained: "'In looking at all the studies to date related to the potential contribution of rosiglitazone to increasing the risk of heart attack, the data are inconsistent and the conclusions are not clear.'" *Id.* (quoting Defs.' Exh. 15, von Eschenbach Statement, at 4). The Court correctly concluded that "the [FDA's] statements referred to in the amended complaint do ***not*** show that the heart attack risk was either statistically significant or sufficiently serious and frequent to affect future earnings." *Id.* at *7 (emphasis added). Thus, even if the Court properly considered as true plaintiffs' "new" conclusory averments that GSK's meta-analyses results were statistically significant – despite the absence of any "newly discovered evidence" and the FDA's own public statements to the contrary – the allegation would not change the ultimate outcome

here. Simply put, plaintiffs' "new" allegations, like their previous allegations, fail to establish a duty to disclose and, therefore, would not change the outcome of the Court's prior judgment.

2. Plaintiffs Have Presented No Basis For Reconsidering The Court's Holding That They Have Failed To Plead A Strong Inference Of Scienter

Plaintiffs' motion to reconsider also should be denied for the separate and independent reason that plaintiffs' other proposed allegations are neither "newly discovered" nor sufficient, either singly or collectively, to supply a strong inference of scienter.

First, plaintiffs' alleged "evidence" regarding GSK's alleged intimidation of Dr. Buse is neither "newly discovered" nor likely to change the outcome of the judgment. Indeed, this Court has already found that the information regarding GSK's alleged intimidation of Dr. Buse (Pls.' Br. at 2-3) is not "newly discovered." *Borochoff*, 2008 WL 2073421, at *10 n.3. Plaintiffs submitted this information in response to defendants' motion to dismiss and in support of their request for leave to amend. *Id* at 10. Moreover, the information was fully vetted by the parties, and was considered by the Court when it decided defendants' motion and ruled that permitting amendment would be futile. *Id.* Indeed, the "new" allegations about Dr. Buse are immaterial to the scienter analysis because the alleged interactions between the Company and Dr. Buse occurred well over five years before the events giving rise to this action, including years before the meta-analyses at issue in this dispute were even in existence. Accordingly, the Dr. Buse allegations cannot support any plausible inference of scienter regarding the nondisclosure of the meta-analyses, let alone a strong one.[6]

[6] As defendants explained in their motion to dismiss papers, these alleged interactions concerned Dr. Buse's admitted speculation – not conclusions – at the time, in the absence of any studies, that there "may" be a connection between Avandia and cardiovascular risks. And while the interactions reflect GSK's disagreement with what it viewed to be that unfounded speculation, they do not remotely constitute an acknowledgment by GSK that any such risk actually existed. (*See* Defs.' Reply Br. at 13 & n.7.)

Second, plaintiffs' proposed new information regarding the alleged "dramatically declining sales of Avandia" is not "newly discovered"; nor would it change the outcome of the judgment. As plaintiffs themselves point out, on October 24, 2007 – three weeks before plaintiffs filed their Amended Complaint on November 13, 2007 – GSK "announced that it would be implementing layoffs and cost cuts after a ***38%*** drop in sales of Avandia significantly hurt the Company's third quarter earnings." (Pls.' Br. at 4-5 (emphasis added).) Thus, such information was readily available to plaintiffs before they filed their Amended Complaint had they exercised a modicum of due diligence.

Moreover, the mere fact that GSK experienced a decline in Avandia sales months after the putative Class Period, and following the controversy caused by Dr. Nissen's article and other new developments, does nothing at all to support a strong inference of scienter, and, therefore, would not change the outcome of the Court's decision. Significantly, plaintiffs do not propose any "new" factual allegations demonstrating that *during* the Class Period GSK expected any such decline. Instead, plaintiffs contend that the sales of Avandia later declined "due to Nissen's meta-analysis and the FDA's safety alert." (Pls.' Br. at 4.) Moreover, plaintiffs' speculative "fraud by hindsight" argument – that the drop in sales after these new events somehow suggests an inference that defendants were motivated to conceal GSK's meta-analyses – conflicts with the public record facts that GSK fully disclosed its meta-analyses to the FDA and posted the data on its publicly available website. As the Court has explained:

> Allegations of defendants' intent to defraud by suppressing negative data are inconsistent with defendants' disclosure of that data on GSK's website and to the FDA. GSK disclosed its meta-analyses results to the FDA, and posted them to its website, which rebuts any intent to defraud by concealing information.

Borochoff, 2008 WL 2073421, at *8. Nothing in the proposed amendment alters the validity of that prior analysis.

Finally, the FDA's March 25, 2008 warning letter to GSK also fails to provide a basis for vacating the Court's judgment. (*See* Pls.' Exh. C, FDA Warning Letter to GSK.) To begin with, the FDA posted the warning letter on its website on April 8, 2008, more than a month before the Court issued its decision on defendants' motion to dismiss. The letter received immediate attention from the media. (*See, e.g.*, Jeanne Whalen & Jennifer Corbett Dooren, *FDA Warns Glaxo Over Lack of Reports on Avandia,* Wall St. J., Apr. 9, 2007, at B3 (hereinafter "*WSJ* FDA Warning Article"), appended hereto as Exhibit B.) Yet, plaintiffs chose not to submit the warning letter to the Court in advance of its May 9 ruling; nor did they, at that time, seek leave to amend on the basis of this alleged "new" evidence. Thus, plaintiffs' after-the-fact argument that the letter somehow constitutes "newly discovered" evidence is disingenuous and should be rejected. *See ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 57 (1st Cir. 2008); *Pugh v. Tribune Co.*, 521 F.3d 686, 698 (7th Cir. 2008).

Most importantly, even if considered "newly discovered," the FDA's warning letter would not have changed the outcome of the Court's judgment because it does not even pertain to the GSK meta-analyses plaintiffs claim defendants had a duty to publicly disclose. Instead, as the letter itself makes clear, the FDA's "warning" pertains to GSK's purported failure to comply with certain administrative requirements for reporting on the status of certain post-marketing clinical trials. (*See generally* Pls.' Exh. C, FDA Warning Letter.) Defendants' alleged nondisclosure of GSK's meta-analyses, however, is the ***only*** alleged securities violation plaintiffs have asserted and, therefore, is the ***only*** relevant subject for scienter purposes. As the PSLRA makes clear, the existence of a "strong inference" is not some free-floating inquiry but must be analyzed with respect to the specific violation alleged. *See* 15 U.S.C. § 78u-4(b)(2)

(2008) (requiring a "strong inference" with respect to "each" act or omission claimed to constitute a violation).

In fact, GSK submitted the Final Reports of its meta-analyses data to the FDA, and posted the results on its publicly available Clinical Trial Register, long before the inspection resulting in the FDA's warning letter took place.[7] Indeed, by May 21, 2007 – three months before the inspection – the FDA had sufficient information to issue its safety alert regarding Avandia and cardiovascular risks, and by the time the inspection concluded on November 13, 2007, the FDA had sufficient information upon which to base a boxed warning, which it announced the next day. (*See, e.g.,* Defs.' Opening Br. at 5, 24-25.) Moreover, according to FDA spokeswoman Susan Cruzan, any additional study results GSK submitted as a result of the inspection "'did not change FDA's determination' that there is 'inconclusive' evidence about an increased risk of heart attacks." (Exh. B, *WSJ* FDA Warning Article.)[8]

In short, the FDA's warning letter hardly supports a strong inference of scienter with respect to GSK's purported failure to disclose the meta-analyses to the public. By the time the FDA commenced its investigation resulting in the warning letter, GSK had already fully disclosed the meta-analyses data to the FDA and posted the results on its Clinical Trial Register. Thus, plaintiffs' proposed allegations regarding the FDA's warning letter are "inconsistent with defendants' disclosure of that data on GSK's website and to the FDA," and such disclosure

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[7] GSK provided the FDA with the Final Reports for its meta-analyses and Balanced Cohort study in August 2006, ***one year*** before the inspection began on August 20, 2007, and posted the results on GSK's Clinical Trial Register ***ten months*** before the inspection. (*See, e.g.,* Pls.' Exh. C, FDA Warning Letter at 1; Defs.' Opening Br. at 41 (quoting Defs.' Exh. 15, von Eschenbach Statement at 3-4); Defs.' Exh. 45, Results from GSK Meta-Analysis and Balanced Cohort Study, at 8.)

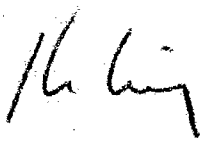
[8] *See also WSJ* FDA Warning Article (explaining that GSK spokeswoman, Nancy Pekarek, said the Company provided the FDA "with all of the missing information in September [2007]," and that the Agency "'had all the information [it] needed to inform [its] decision making on the label.'").

"rebuts any intent to defraud by concealing information." *Borochoff*, 2008 WL 2073421, at *8. Because these "new" averments do not support an inference, much less a strong inference, of scienter, they do not provide a valid basis for vacating the Court's prior judgment.

III. CONCLUSION

For all of the above reasons, defendants respectfully request that the Court deny plaintiffs' Motion for Reconsideration of the Court's May 9, 2008 Opinion and Order.

Respectfully submitted:



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